

Exhibit B

Case #3229/3230 (08/01/95)

THE OPTIVA CORPORATION

The Sonicare® Toothbrush

In-House

- **If an advertiser relies on in vitro laboratory testing to substantiate a claim, this fact should be conspicuously disclosed in the advertisement**
- **Well controlled in vivo clinical studies can form the basis for non-comparative performance claims**
- **Survey results should accurately convey the nature and scope of the survey sample**

Basis of Inquiry: In two separate and distinct actions, the Sonex Corporation (“Sonex”) and Braun Inc. and Braun AG (“Braun”) challenged the truth and accuracy of print, radio, and television (in the form of an infomercial) advertising for the Optiva Corporation’s Sonicare® toothbrush.

Though these challenges were received separately, the timing of these respective filings was relatively concurrent. In light of this, the NAD decided to consolidate the proceedings and consider the issues and concerns raised by the challengers as distinct aspects of one comprehensive case. The two challenges were handled separately. The timing of the correspondences and the reporting of this decision were the only “shared” elements of this proceeding.

The Optiva Corporation had previously participated in a self-regulatory review of similar advertising (See, The Optiva Corporation, NAD Case Reports, Vol.24, No.3, p.45, May, 1994). That inquiry was a result of NAD’s monitoring program, and the advertiser had taken the NAD’s concerns into consideration in formulating its new advertising. For the purposes of the present inquiry, Optiva was asked to address the allegations raised by two of its competitors as they pertain to its new advertising.

The following claims are representative of those that formed the basis of this inquiry:

A. From the print advertisement in “The Sharper Image” catalogue entitled “Introducing New Sonicare Quadpacer Toothbrush”

1. “Sonicare emits high-frequency sonic waves for ‘beyond-the-bristles’ cleaning.”
2. “Research studies show this innovative health care system removes periodontal bacteria up to 4mm beyond the bristles.”
3. The boxed section titled: “Remove 80% of stains” including the before and after photos of stained teeth.
4. “Vibrating so fast, ... scours away stains and food particles clinging to teeth. The high frequency sweeping motion produces fast-moving micro-size bubbles that travel through the toothpaste foam into nooks, fissures, cracks, pits and periodontal pockets - all the places plaque-causing bacteria grow.”
5. “The Sonicare foam reaches deep for total cleaning and brightening - but without the unpleasant scrape of a dental tool.”
6. “One Michigan dentist writes, ‘I have never used an instrument which so totally removes plaque.’”
7. “Sonic waves remove plaque and stains.”

B. From the professional print advertisement entitled “Attack Plaque Bacteria Beyond- the-Bristles”

1. "Sonicare is the first sonic toothbrush that generates 31,000 bristle sweeps per minute to create mild cavitation that's shown in laboratory studies to remove harmful plaque bacteria up to 4mm beyond the bristle tips."
2. "Sonicare surpasses direct brushing technology to sonically clean teeth."
3. "Since even the best manual and electric toothbrushes only clean by actual bristle contact, untouched plaque may remain where bristles don't reach. Sonicare has a unique technology that sends gentle vibrations through toothpaste so it reaches far beyond, for effective cleaning in high risk areas."
4. "Which is why 98% of the dental professionals who have tried Sonicare recommend it."
5. "Plus, dental professionals who have tried Sonicare prefer it to Inter Plak, Braun Oral-B, Water Pik or Rota-dent."
6. "And find out why 92% of dental professionals who tried it prefer Sonicare for their own use."

C. From the print advertisements making the 30-day free trial offer:

1. "A clinically proven sonic innovation that takes oral care a step beyond."
2. "Gently removes over 80% of coffee, tea and tobacco stains for naturally whiter teeth."
3. "Recommended by 98% of dental professionals who have tried Sonicare."
4. "ADA-accepted Sonicare is the first sonic toothbrush that generates gentle sonic vibrations, transforming any toothpaste into the penetrating foam."
5. "92% of dental professionals who have tried Sonicare prefer it for their own use."
6. "Achieve a more complete cleaning in high risk areas."

D. From the direct mail solicitation letter to Paul Harvey listeners:

"In university-conducted clinical studies, Sonicare was proven to remove three times more plaque than ordinary brushing."

E. From the Sonicare brochure:

"Sonicare has been shown to remove more than twice as much plaque as manual brushing."

F. From the infomercial:

1. Dr. Baab's statement that bacteria develop in periodontal pockets, attach to [or attack] the root of teeth, and cause root cavities which lead to tooth loss, followed by the statement that Sonicare removes plaque from the pockets, beyond the reach of the bristles.
2. "It's clinically proven to reverse gingivitis, while reducing plaque bacteria in periodontal pockets. Which is why 98% of the dental professional who have tried Sonicare recommend it."

G. From various forms of advertising:

The characterization of the Sonicare toothbrush as a sonic device.

THE SONEX CHALLENGE

The Sonex Corporation's Postion:

Sonex challenged Optiva's advertising alleging that it: (i) contained inaccurate representations of the clinical trials relating to plaque removal and gingival health; (ii) contained inaccurate representations and portrayals of "beyond-the-bristles" plaque removal, "below the gumline" removal of bacteria, and disruption of bacterial fimbriae; (iii) incorrectly characterized the Sonicare toothbrush as a "sonic" device; (iv) inaccurately compared the Sonicare toothbrush to professional dental cleaning devices and processes, like flossing; (v) made references to a flawed survey of dental professionals; and, (vi) contained unfounded superiority- claims.

I. Sonex's allegation that Optiva's advertising contained inaccurate representations of the clinical trials relating to plaque removal and gingival health

The challenger argued that claims of "two times" or "three times" the plaque removal with Sonicare misrepresented the actual findings of the clinical study upon which the advertiser relied. According to the challenger, the post-brushing Plaque Index scores, recorded during this study reflect a maximum plaque removal of 48% for the manual brush and 54% for the Sonicare. These percentages negate the literal accuracy of claims of "three times" or "two times more plaque removal with Sonicare."

Sonex asked an independent research expert to evaluate the report of this study, which was published in the *Journal of Periodontology*. He concluded that this study does not measure plaque removal. He observed that since no baseline pre-brushing data was provided the amount of plaque removal cannot be determined.

The challenger rationalized that the only mathematical possibility that would explain the "three times as much" claim would be if the advertiser compared the post-brushing scores at baseline, or initial brushing, to the post-brushing scores at the 4-week evaluation. The difference in scores from the first week to the fourth week was 0.48 for the Sonicare and 0.15 for the manual brush users. Therefore, the "change" in post-brushing scores for Sonicare is three times as much as the "change" for the manual brush users. The challenger argued that this is not a measurement of plaque removal. According to the challenger, plaque removal is a "single event measurement, and it is not time related from week to week." The challenger argued that the study proves a change in the post-brushing scores in time and nothing else. The study does not prove how much plaque was removed, and which brush has removed more plaque.

Sonex maintained that if a device does a significantly better job of removing plaque, then it will produce significantly "better improvements" of gingival and bleeding scores within four weeks of use. It observed that Sonicare did not produce "better improvement" of the gingival and bleeding scores than the manual toothbrush. The challenger's expert observed that "any benefit of the Sonicare toothbrush related to gingival health appears to be no different from that observed with a manual toothbrush." Consequently, Sonex also argued that the claim "...your gums will be healthier," is excessive and is not supported by clinical data.

II. Sonex's allegation that Optiva's advertisements contained inaccurate representations pertaining to "beyond-the-bristles" plaque removal; removal of bacteria below the gumline; and "damage to bacterial fimbriae"

The challenger argued that the claims that Sonicare cleans "beyond-the-bristles," "cleans below the gumline," "removes plaque in the periodontal pockets," and particularly that it can achieve these results on surfaces 4mm away from the bristle tip, infer clinical in vivo results, but are not supported by in vivo clinical data.

A. Beyond-the-Bristles plaque removal and Removal of bacteria below the gumline

Sonex's position is that the in vivo plaque removal data on which the advertiser relied as support of its "beyond-the-bristles" claims is entirely based on mechanical scrubbing. It argued that the advertiser must isolate the "dynamic fluid motion" effect of its brush from the mechanical scrubbing, before the "beyond-the-bristles" plaque removal claim can be made.

Additionally, Sonex contested Optiva's characterization of the sloshing water motion created by the vibrating bristle as "dynamic fluid activity" that removes plaque "beyond-the-bristles"™. It declared that while Optiva has shown, in laboratory tests, that the Sonicare toothbrush generates fluid motion in a water tank utilizing "high density water bath," it has not shown that this dynamic fluid activity occurs in the oral cavity, in the presence of low density foaming toothpaste.

Sonex criticized Optiva's reliance on the study titled "Ability of the Sonicare Electronic Toothbrush to Generate Dynamic Fluid Activity that Removes Bacteria," which was published in the Journal of Clinical Dentistry, as support for its claims that the Sonicare can remove bacteria beyond-the-bristle tips. Though the challenger acknowledged that in vitro laboratory studies have demonstrated that it is possible to dislodge bacterial colonies from flat artificial surfaces, it argued that "this observation cannot be used to support or imply a clinical performance." To support such a claim the challenger argued, "would require a clinical evaluation in vivo that demonstrates the removal of plaque without being touched by the bristles."

The challenger's expert stated that the "geometrical differences between the human mouth and the flat surface used in this study invalidate the extrapolation of the results of this in vitro study to the human condition."

B. Damage to bacterial fimbriae

The challenger also pointed out that the infomercial contained animation depicting the fimbriae or "legs" of the bacteria separating from the body of the bacteria. It argued that cutting the bacteria's legs has not been proven. It noted that the published in vitro study on which Optiva relied as support of this representation used an industrial acousticgenerator operating at 50kPa. The challenger argued that the Sonicare can not generate dynamic fluid motion equivalent to 50kPa.

C. The demonstration of Sonicare's effects as depicted in the advertising

The challenger argued that the demonstrations depicted in the advertising which show the foaming action reaching through the spaces between the teeth of a dental model were flawed. First, it argued that the large gaps in the dental model featured in the infomercial are not typical, they are rare. Additionally, it stated that there is no "waterbath" effect in the mouth, like the one created by the dam at the back of the model arch. It argued that the demonstration does not represent a typical human condition.

Though it acknowledged that "a person can agitate saliva through the gaps between the teeth," it argued that this does not remove plaque. In other words, it argued that even if foam could come through without the "water tank" effect, "clinical efficacy of this foam has not been proven."

III. Sonex's allegation that the advertising incorrectly characterized the Sonicare toothbrush as a "sonic" device:

The challenger observed that the print advertisements and the infomercial show an artist's rendition of sonic waves emitting from the tip of the bristles penetrating through teeth and gums. Sonex maintained that "there is no sonic emitter *per se* in the Sonicare."

The challenger charged that there is no sonic transducer in the head of the Sonicare toothbrush. What it sees is a torsional pivot pin on the stem of the toothbrush head. This pivot pin does not generate sonic waves and does not transfer sonic waves to the bristles. The 260 Hz frequency of the motion of the brush stem is generated by the electromagnet in the handle. Though it acknowledged that the toothbrush head vibrates in the frequency range that is considered to be a sonic frequency range, it added that all electric toothbrushes on the market vibrate or rotate in this range, i.e., 20-20,000 Hz. It maintained that the Sonicare toothbrush is a standard electric toothbrush which vibrates faster than earlier models on the market.

According to the challenger, to support the assertion of any clinically meaningful "sonic effect of the Sonicare toothbrush, it is incumbent upon the [advertiser] to execute a study *in vivo* that isolates and solely evaluates the effect of the sonic component of [its] brush" from the high speed mechanical vibration of the device.

It was the challenger's position that plaque removal is not dependent upon time but rather relates to the number of brush strokes. It maintained that in order to detect the beneficial effects of the "sonic" waves in the dentifrice or saliva generated by a vibrating brush, one must assure that the same amount of mechanical scrubbing is administered by both the manual control brush and the vibrating "sonic" brush. It reasoned that if there is a "sonic" effect, the "sonic" brush should do significantly better when the same number of mechanical scrubbing strokes are administered. According to Sonex's suggested protocol, the way to isolate the sonic effect is to have the control group use the "sonic" brush as a manual toothbrush (without turning the power on) for three minutes. The test group should use an activated "sonic" brush, and run it for the length of time that will provide the same amount of mechanical scrubbing as when the brush is used manually (not powered). Since the Sonicare operates at 31,000 strokes per minute, and is advertised as running 150 times faster than a person can wield a manual brush, Sonex suggested that the powered Sonicare should be used for only 1/150 of the time allowed for the manually used Sonicare. This would allow the activated Sonicare to be used for 1.2 seconds versus 180 seconds for the manually used Sonicare. Since 1.2 seconds would not allow for time to cover all surfaces, the challenger suggested that, to be fair, the test should allow the activated Sonicare to be used for 20 seconds.

Sonex conducted a trial using this suggested methodology. It reported that according to this trial, the "manual" Sonicare removed twice the amount of plaque in three minutes than the activated Sonicare did in 20 seconds. It argued that if there had been any "sonic" effect, the activated Sonicare would have removed more plaque than the manually used Sonicare, not less.

IV. Sonex's allegation that the advertising inaccurately compared the Sonicare toothbrush to professional dental cleaning devices and processes, like flossing

Sonex argued that certain statements contained in the advertising (e.g., "stop brushing your teeth. Use Sonicare instead. The dentists preferred way of cleaning teeth. Not with scrub brushing but with sound waves" and "...two minutes with [Sonicare] was about equal to a consistent flossing and brushing program,"...) are contradictory to the ADA's position on brushing and flossing.

V. Sonex's allegation that the advertising made references to a flawed survey of dental professionals:

Sonex argued that the survey of dental professionals mentioned in the advertising was not random and that its methodology was flawed. It deduced that dentists were eliminated from the survey if they returned the Sonicare toothbrush, while the ones who did not return their purchased Sonicare were provided with an expensive inducement [a free Sonicare] to fill out the survey."

The challenger speculated that those who did not like it, but kept it, would not take the time to respond to the multi-page questionnaire. Only the ones who liked it enough to want another unit (and get a third free) filled out the survey.

VI. Sonex's allegation that the advertising contained unfounded superiority claims

Sonex listed the following statements as just a few of the examples of what it considered to be "unfounded superiority claims:"

"reducing gingival pocket depth;" "your hygienist will find less plaque and you'll have less of that dreaded scraping;" "no more plaque;" "remove plaque and tartar," "better than any toothbrush;" "unmatched reliability" "best technology" "nothing removes plaque and stains like Sonicare."

Sonex's argument was based on the fact that it was not aware of any "competitive testing done by Optiva that evaluated all of the manual and electric toothbrushes on the market to establish these superiority claims."

The Optiva Corporation Response To The Sonex Challenge:

Optiva provided the following background information on its product. It developed the Sonicare toothbrush from technology initiated in 1984 at the University of Washington during the course of studies on the effects of sonic vibrations on oral bacteria. The National Institute of Health supported the development of Sonicare by providing Optiva with two Small Business Innovation in Research grants. Optiva received FDA approval to market the Sonicare in 1992. In 1994, the American Dental Association (ADA) conferred on Sonicare its seal of acceptance. Optiva informed the NAD that all of Sonicare's current advertising claims have been reviewed and approved by the ADA.

I. Optiva's response to Sonex's allegation that Optiva's advertising contained inaccurate representations of the clinical trials relating to plaque removal and gingival health

Since many of the ads which Sonex cited on this issue had been discontinued by the advertiser prior to this inquiry, the advertiser only addressed the claims currently in use.

Relying on the study conducted by Drs. Johnson and McInnes, which is referred to in the advertising, the advertiser argued that Sonex's assertion that Sonicare does not remove significantly more plaque than a manual brush was false.

Optiva mentioned that this study by Drs. Johnson and McInnes, which was published in *the Journal of Periodontology*, was found to be "a well-done study" by the journal's statistical reviewer. Additionally, Optiva obtained an independent review of this paper from a biostatistician/periodontist. His report confirming Optiva's position was submitted to the NAD.

Optiva also provided the NAD with two additional studies which confirmed this challenged study. Reports of all three clinical studies were submitted to show that Sonicare provides statistically superior plaque removal to manual brushing, while significantly reducing gingivitis. The second of these studies was also conducted by Drs. Tritten and Armitage at an independent research university. It was not published, but was submitted to the NAD for its review. According to its results, the sonic toothbrush proved statistically superior on a percentage reduction basis in removing supragingival plaque from the dentition taken as a whole and was particularly better in hard-to-reach areas. Sonicare and the manual brushes were found to be equally effective in reducing gingival inflammation.

The third clinical study was conducted by a private practitioner (orthodontist). This study was done on 32 patients, 18 of whom used the Sonicare and 14 used the manual toothbrush. It showed that Sonicare reduced plaque by approximately 20% over a 12-week study period. The manual group improved by 6%. Therefore, the advertiser argued that Sonicare showed a greater than 3-fold superiority over the manual toothbrush group. The Sonicare group showed an overall improvement in gingival health during this study, while the manual group did not.

The advertiser defended its reliance on and interpretation of the findings of the *Journal of Periodontology* study. It explained that it is scientifically and clinically appropriate to evaluate plaque reduction over several weeks of time in a trial of a new dental hygiene tool like the Sonicare. This is because there may be an initial “novelty effect,” i.e., an initial period during which the patients/subjects are learning how to use the device most effectively.

Johnson & McInnes studied a sample of 51 adults, randomly assigned to either a manual brush or the Sonicare. They asked (i) which brush results in the least amount of plaque after a 2-minute brushing, and (ii) which brush resulted in the greatest reduction from the initial post-brushing plaque score over the 4-week period. The answer to the first question was that the Sonicare brushing resulted in significantly less plaque than brushing with a manual brush for 2 minutes. The answer to the second question was that, on average, the Sonicare plaque reduction was three times that of a manual brush over a 4-week period.

The advertiser recognized that the “rate of plaque removal” –as defined by the challenger— pre-brush scores minus post brush scores—is one way of conducting a study, but it is not the only valid way to determine plaque reduction. The goal of Optiva’s study was to evaluate the level of plaque remaining after timed two-minute brushing on multiple occasions over a 4-week test period, to take into account the dynamic, biological aspect of plaque formation.

Additionally, the advertiser explained that while it is well established that gingival inflammation is directly correlated with plaque accumulation, it is a general - not an absolute correlation. Moreover, the Gingival Index and the Bleeding-on-Probing test are independent relative indices. The advertiser referred to other studies that have reported that there can be significant differences in plaque reduction between oral hygiene products, without statistically significant differences in gingivitis and/or bleeding scores. The published Johnson & Meinnnes study reported that both Sonicare and the manual brush users showed statistically significant and consistent reductions in gingival index and sulcular bleeding index scores with time. The data from the unpublished Tritten and Armitage study (mentioned above) indicated that using Sonicare leads to a statistically significant reduction in gingivitis, and that this reduction is not significantly different from the manual control.

II. Optiva’s response to Sonex’s allegation that Optiva’s advertisements contained inaccurate representations pertaining to “beyond-the-bristles “plaque removal; removal of bacteria below the gumline; and damage to bacterial fimbriae”

The advertiser’s substantiation for its beyond the bristles claims consisted of the following: (i) documentation of the in vitro removal of bacteria from dental surfaces by fluid dynamic forces achieved at distances of 2–4mm beyond the tips of the bristles (as well as justification of the hydrodynamic relevance of this in vitro dental model through comparative pressure measurements taken at both the test chamber and on a model of the mouth); (ii) two studies documenting reduction in numbers of subgingival bacteria from periodontal pockets in vivo; (iii) a report from independent researchers on the in vitro removal of human plaque, grown in vivo on enamel surfaces; (iv) a report on the damage to fimbriae, bacterial adherence structures, through the fluid dynamic forces of the Sonicare; and, (v) a video taped presentation comparing test-tank and human brushing demonstrations for Sonicare and several other devices.

A. Beyond -the-Bristles plaque removal

The advertiser has sponsored numerous studies that investigated Sonicare’s ability to clean oral surfaces beyond the reach of its bristles. The protocol of the first studies involved growing plaque bacteria and allowing them to adhere to acceptable model dental surfaces, like titanium or hydroxyapatite. The surfaces were then held in fluid below the reach of the Sonicare bristles and exposed to the “sonically-induced fluid forces.” The results of these studies were submitted to show the beyond-the-bristles fluid activity generated by Sonicare and the reduction of plaque bacteria on these surfaces from varying exposure distances. Under these controlled conditions, the bristle to surface distance was varied in order to establish the zone in which effects could be observed.

The advertiser explained that the in vitro evaluations upon which it relied were clinically relevant to the buccal surfaces of the teeth where the bristles are not in direct contact with the tooth surface. In both in vitro and in vivo cases, a thin film of fluid interfaces between the bristles and the surface: water in the case of the published research; toothpaste foam and saliva in normal brushing.

The advertiser presented a report to show that the sonic pressure created in the test-well used in the laboratory plaque and bacteria removal studies was found to be similar to that on the facial tooth surface of the typodont model. The advertiser indicated that this in-vitro model of the fluid force that occur in the oral cavity, was conservative because the fluid pressures in interproximal regions (hard to reach plaque creating areas between teeth) were actually higher than on the more flat, exposed straight buccal and lingual tooth surfaces.

Another study examined (in vitro) the ability of the Sonicare toothbrush to remove actual dental plaque accumulated in vivo in human enamel samples positioned within an intraoral device. Sonicare was found to create sufficient fluid activity to remove plaque bacteria without direct bristle contact. Significant and reproducible removal of 68% of the bacterial plaque was achieved relative to the control (untreated) surface upon a 10 second exposure to the brush at a distance of 2mm from the enamel surface.

The advertiser also submitted the results of an in vitro bacterial removal comparison of Sonicare, Interplak® and UltraSonex®. According to this report, "since the Sonicare was the only device that produced cavitation and dynamic fluid activity, the results suggest[ed] that this fluid movement is an important factor in removal of bacteria from oral surfaces when the bristles do not contact the surface being affected."

B. Removal of bacteria below the gum/me

Optiva has sponsored two studies on the reduction of bacteria in periodontal pockets. In the first study, use of Sonicare for two weeks reduced the number of bacteria in 88% of the 20 periodontal pockets tested. In the second study, Sonicare use was shown to significantly reduce the numbers of pathogenic bacteria from periodontal pockets over an 8-week study period. The advertiser informed the NAD that based on these studies, the ADA has approved Optiva's advertising language on below the guinline performance.

C. Damage to bacterial fimbriae

The advertiser maintained that the critical factor in fimbriae damage is shear forces generated by the fluid activity, not the amount of pressure (50 kPa). An electronmicroscopic study showed that exposure to the sonic toothbrush shortened and/or removed the fimbriae of bacteria, thereby decreasing their ability to adhere to a model surface. This study, which was reported in *Oral Microbiology and Immunology* examined the physical effects of low frequency acoustic energy on oral bacteria. A bacterial suspension was exposed to acoustic energy from a lab acoustic generator (50kPa, 200 Hz) and from the Sonicare. The findings of this study indicated that the shear forces from these acoustic levels were sufficient to remove bacteria adherent to a model dental surface. The shear forces occurring in the exposed fluid due to bubble activity and fluid flow were the likely causes of damage to the sensitive surface structures on the surfaces of the bacteria. The researchers concluded that these results support the concept that an electronic toothbrush employing low-frequency acoustic energy may help prevent and control periodontal diseases by altering bacterial adherence.

D. The demonstration of Sonicare's effects as depicted in the advertising

The advertiser stated that the gaps between the teeth in the dental model used in the infomercial are not rare, especially among patients who have suffered from periodontal diseases. It informed the NAD that at least 20% of the adult population of the US suffer from severe periodontal disease. Since many people who might consider purchasing a Sonicare are those who have had periodontal problems or extensive restorative dental treatment, use

of this model was, according to the advertiser, appropriate and educational. It argued that the movement of fluid through these gaps would not have appeared greatly different if the gaps had been smaller.

The advertiser also defended against the challenger's assertion that water or fluid is not present in vivo. The advertiser explained that the human oral cavity is constantly bathed in saliva which flows into the oral cavity at a rate of 5-2 ml/min. Additionally, the Sonicare owner's manual instructs users to wet the bristles before use and to keep fluid in their mouths while using the Sonicare. It, therefore, maintained that the amount of water (2-3 ml) that the advertiser added to the typodont for experimental and demonstrational purposes was reasonable, and not unrepresentative.

III. Optiva's response to Sonex's allegation that the advertising incorrectly characterized the Sonicare toothbrush as a "sonic" device:

The advertiser explained that the Sonicare includes a sonic transducer in its head which generates an audible sonic frequency (260Hz, i.e., middle C). This transducer drives the bristles at this sonic frequency with a bristle amplitude sufficient to produce the fluid dynamic effects (described above). The advertiser reasoned that the "sonic brush" terminology is completely valid, since the Sonicare uses sound waves to achieve the "beyond-the-bristles"™ aspect of its performance. The unique Sonicare technology is protected by a number of patents.

The advertiser referred to the dictionary definition of "sonic" as "having a frequency within the audibility range of the human ear...." or "utilizing... sound waves." It asserted that Sonicare is accurately termed a "sonic" device since it utilizes sound waves in its operation. The advertiser added that confirmation that these sonic vibrations emanate from the brush head can be obtained by noting that the powered handle is virtually noiseless when operated without the head.

The advertiser argued that Sonex's assertions are based on a narrow definition of what constitutes a transducer". Optiva cited the following dictionary definition of the word "transducer": "a device that is actuated by power from one system and supplies power in any other form to a second system." This definition fits the Sonicare brush head assembly because: (i) it is a device; (ii) it is actuated by power from one system (the electromagnetic power from the Sonicare handle); and (iii) it supplies power in another form to a second system (the sonic vibration of the bristles).

Sonic bristle motion and the sonically-induced fluid dynamic effects of the Sonicare are interdependent and exist simultaneously in the mouth. Optiva submitted a video taped in vivo demonstration of these effects. The Sonicare bristles both scrub the surface of the tooth in a conventional toothbrush manner, and produce a dynamic fluid motion that removes bacteria. The dynamic fluid activity is created by the sonically moving bristles.

The advertiser therefore, believes that it is justified in its use of animation depicting sonic waves to illustrate for consumers that the Sonicare is different from other products. The advertiser pointed out that the drawings and video animation do not show penetration of the sonic waves through teeth or gingiva, but rather are overlayed on these structures, as they would pass over such structures in vivo.

IV. Optiva's response to Sonex's allegation that the advertising inaccurately compared the Sonicare toothbrush to professional dental cleaning devices and processes, like flossing

The advertiser asserted that it has never stated or implied that Sonicare was comparable to a dental scraper. It affirmed that Paul Harvey's comments have been permanently withdrawn.

The statement made by Dr. Whitaker about flossing reflected his personal experience and was not endorsed by or disseminated by Optiva. The advertiser informed the NAD that prior to this inquiry it had notified the publishers

of the newsletter, in which Dr. Whitaker's editorial appeared, that it must publish only ADA-approved copy. Optiva emphasized that its position on flossing is identical to that of the ADA — floss daily.

V. Optiva's response to Sonex's allegation that the advertising made references to a flawed survey of dental professionals

The advertiser defended the methodology of its study and accuracy of the claims that stem therefrom (e.g., "96% of the dental professionals who have tried Sonicare recommend it to their patients.") It asserted that the methodology of the survey upon which its claims of professional recommendation were based has been accepted by the ADA and has been misinterpreted by the challenger.

The advertiser clarified certain matters that the challenger seemed to have misunderstood. Specifically: (i) All dentists who purchased Sonicare were mailed the survey, two weeks after the trial unit was delivered; (ii) Only 2% of the purchased trial units have been returned. Therefore, the assertion of sample bias due to elimination of professionals who return their units is of negligible consequence; and (iii) The advertiser did not offer a free unit as an incentive. It offers a free unit *with the purchase* of at least one additional unit.

Of the dental professionals who were contacted, over 4,000 responded. A response rate was achieved that is well within the range of industry norms for mail surveys in general and especially good for surveys of dental professionals, as attested to by a consumer research expert.

The updated results of this ongoing survey reflect that 98% of the dental professionals who responded to the survey would recommend Sonicare (60% to most patients and 38% to some patients).

The advertiser pointed out that the universe for these claims is dental professionals "who have tried Sonicare" and is identified as such by the claim itself. Since every dental professional who tried the product was sent a survey and a representative sample of those professionals responded to the survey, the advertiser argued that the results of the representative sample may be extrapolated to the universe surveyed.

VI. Optiva's response to Sonex's allegation that the advertising contained "unfounded superiority claims"

The advertiser pointed out that many of the examples cited by the challenger as "unfounded superiority claims" had been voluntarily discontinued prior to this inquiry. It noted that the challenger presented no evidence to show that consumers or professionals interpret these claims as claims of superiority. The advertiser nevertheless, did take the opportunity to address several individual claims. For example:

The "unmatched reliability" claim: The advertiser claimed that Sonicare's reliability has been exceedingly high because of its solid state design, with only one moving part. Fewer than 1% of units have been returned for product failure during the past 12 months.

The "best technology" claim: Though this claim is no longer used, the advertiser defended that it considers this "puffery" that is nevertheless supported by Sonicare's patented technology.

"Nothing removes plaque and stains like Sonicare," and "no mechanical toothbrush cleans like Sonicare": The advertiser pointed out that no product uses Sonicare's unique frequency brushing, patented brush head design, and bristle motion to obtain plaque and stain removal.

NAD's Decision As To The Sonex Challenge

Since the advertising in question contained such a wealth of information, it was impractical, if not impossible, for the NAD to address the challenger's concerns on a claim by claim basis. Rather the NAD's findings were based on the broader issues (for they encompass the individual claims) that were disputed by the parties.

I. The issue of whether the advertising inaccurately represented the clinical trials relating to plaque removal and gingival health

Like the advertiser, the NAD acknowledged that there is more than one way to assess plaque reduction. One way, advocated by the challenger, would be to compare the pre-brush scores to the post-brush scores of a single session. On the other hand, the advertiser's chosen methodology recognized the dynamic nature of plaque formation and sought to measure overall reduction in plaque over time. It called for evaluating the level of plaque remaining after timed brushing on multiple sessions over time.

Like the challenger, the NAD did not dispute the validity of Optiva's study that was published in the *Journal of Periodontology*; it did not question the credibility of the peer reviewers; and it accepted the fact that the post-brushing scores improved during the course of the study. However, NAD had to consider the manner in which the findings of the chosen study were communicated to the consumer. In other words, the issue was not whether one test was "better" for evaluating plaque removal than the other but rather, whether the claims made in this advertising accurately communicated the findings of the tests upon which the advertiser relied.

The results of the tests submitted by the advertiser indicated that Sonicare achieved superior plaque removal compared to a manual brush while attaining reductions in gingival inflammation similar to that achieved with a manual brush.

The advertising contains claims that specifically refer to Sonicare's superiority in plaque removal. Certain of these claims were specific enough to quantify the amount of plaque removal as "three times" or "two times" more than that achieved by a manual brush. The data submitted by the advertiser supported that over a 4-week period, the percentage difference in the post-brushing scores for the Sonicare users was three times as much as the difference in post-brushing scores of the manual brush users.

NAD realized that one reasonable interpretation of the term "plaque removal" implies "amount" or "quantity." Therefore, the NAD could not ignore the consequent implication that a quantified claim as to plaque removal might reasonably be understood to mean the change in the amount of plaque (either in a single session or over time). The challenger's definition of plaque removal as the result of pre-brush minus post brush scores was not unreasonable. The fact that there are several reasonable interpretations of the term plaque removal, imposes upon the advertiser the duty to provide substantiation for all such interpretations or clearly communicate the parameters of its supporting information.

NAD concluded that there was sufficient evidence in the record to support that Sonicare was statistically superior to a manual toothbrush in terms of plaque removal. However, it suggested that, in order to avoid the inevitable confusion as to the meaning of its terminology, quantified claims like "two times" and "three times" the plaque removal should be modified to reflect the parameters of the tests on which they are based.

NAD noted that claims of improved gingival health were neither comparative nor exclusive. Claims of improved gingival health appeared as simple references to the incidental benefit of a consistent oral hygiene regimen. Improved gingival health was documented with the use of Sonicare, as it was for two-minute brushings with the manual brush. Therefore, NAD found sufficient support for the current claims.

II. The issues of whether the advertising contained inaccurate representations pertaining to "beyond-the-bristles" "plaque removal; removal of bacteria below the gumline; and damage to bacterial fimbriae

A. Beyond the bristles plaque removal

The advertiser provided sufficient support for its contention that the "reach" of the Sonicare extends beyond its bristles. The rapidly moving bristles of the activated Sonicare were shown to generate fluid dynamic activity and cavitation that transcended the physical reach of the bristles. The advertiser documented the existence of these forces in otherwise hard to reach areas of the oral cavity.

NAD did, however, share some of the challenger's concerns about the representation of these findings in the current advertising and the extrapolation of the results obtained through in vitro experiments to claims that implied in vivo effects.

More specifically, NAD observed that though the advertiser submitted numerous studies that confirmed Sonicare's ability to remove plaque (even human plaque grown in vivo) from distances of 2-4 mm beyond the physical reach of its bristles, the effect was not demonstrated in vivo. As stated in the study that was published in the Journal of Clinical Dentistry and was submitted by the advertiser, "the dynamics of brushing in the oral cavity will be different than an in vitro situation, i.e., saliva and toothpaste may alter the fluid dynamics, fluid quantities around the brush head may vary, and bacterial inter-relationships and adherence may be more complex." NAD acknowledged the validity of the in vitro tests, particularly because of the tightly controlled conditions under which they were conducted. NAD also realized that such tightly controlled conditions would be more difficult (if not impossible) to maintain if the plaque or bacterial removal was assessed in vivo. Nevertheless, NAD had to contend with the communication of the claims at issue.

The advertiser (i) documented the fact that the effect (in the form of foaming action, shear forces or pressure) of the Sonicare can be detected beyond-the-bristles; (ii) presented evidence to support the in vitro reduction of plaque also from beyond-the-bristles; and (iii) as discussed above in Section I, demonstrated in vivo, an increase in plaque reduction with the use of Sonicare over time. Though this information was quite compelling, the claims at issue called for one element that was missing, one element that would link these results together, i.e., an in vivo test that would show a reduction of plaque beyond-the bristles. In other words, though the NAD found the "beyond-the-bristles" claim to be substantiated as a stand-alone, mode-of-operation claim, it requested that future claims that imply in vivo plaque removal beyond-the-bristles be modified to clearly state that plaque removal beyond the bristles is based on laboratory studies.

B. Removal of bacteria below the gumline

The challenger noted that the numbers of subgingival bacteria can also be reduced by excellent manual brushing. However, the advertiser, who agreed with this statement of fact, was not making a comparative claim about Sonicare's ability to remove bacteria below the gumline. In the absence of consumer perception evidence to the contrary, the NAD did not find that this claim rose to the level of making a superiority or exclusivity claim. NAD concluded that it was simply a statement of fact that was supported by at least two studies.

C. Damage to bacterial fimbriae

The advertiser presented sufficient support to show that the shear forces generated by the fluid/foam activity surrounding the activated Sonicare were the likely causes of microscopically observable damage to bacterial fimbriae (and the ensuing decrease in adherence of bacteria from model dental surfaces).

D. The demonstration of Sonicare's effects as depicted in the advertising

There were two points of concern relating to the accuracy of Optiva's depiction of the fluid dynamic activity that is the cornerstone of the Sonicare's performance; the fluid contained in the model arch and the size of the gaps of the dental model featured in the advertisements.

The existence of a fluid medium is obviously imperative to the effectiveness of a device that operates by generating fluid dynamic pressure and cavitation. NAD concluded that the advertiser presented sufficient justification for its addition of 2-3 ml of water to the dental model that it used for experimental and demonstrational purposes. It found that a reasonable amount of added water was not unrepresentative of the expected consumer experience with the product.

NAD, however, did find the use of a dental model with atypically large gaps questionable. The size of the gaps was a relevant and legitimate concern because the penetration of cleansing foam *through* these dental spaces was directly related to the product's claimed performance. Therefore, the possibility of overstatement could not be overlooked. Though NAD recognized that 20% of the American population suffers from periodontal disease that can result in unusually large gaps between the teeth, the situation is not typical to the average consumer. Since the advertising is addressed to the typical consumer, the NAD recommended that the advertiser modify these representations with adequate disclosures.

III. The issue of whether the advertiser's characterization of the Sonicare toothbrush as a "sonic" device is accurate within the context of this advertising

The advertiser defended its description of the Sonicare as a "sonic" device that uses electromagnetic power to activate the sonic vibration of its bristles. Since the challenger did not establish that the advertiser's characterization is contrary to consumer or industry understanding, the NAD accepted the advertiser's description of its product as one (albeit more broad than the challenger's) of several acceptable descriptions of the product. The frequency of bristle motion defined the Sonicare as a sonic toothbrush. The sonic bristle motion and the bristle-induced fluid dynamic effects are interdependent and cannot be isolated as Sonex suggests.

Though the NAD found the challenger's suggestion for a test that would isolate the "sonic" effect from the effect of the vibrating bristles to be an interesting theoretical argument, it concluded that it was, for the purposes of this inquiry, flawed and inapplicable to the claims being made. Firstly, the challenger's test ignored the effect of brushing time from the cleaning (or plaque removal) process, which it defined solely in terms of number of brushing strokes. The record seemed to indicate that brushing time was an important variable in the evaluation of plaque removal effectiveness. Complete disregard of this factor weighed against the reliability of the challenger's proposal.

Additionally, a test that purports to distinguish a single aspect of one unit's performance would be best applied to a situation in which the benefits of that single aspect were explicitly and individually promulgated. One such example is the situation pointed out by the challenger, i.e., when comparing a vibrating electric toothbrush to a manual toothbrush, and claiming an adjunct "sonic" effect. However, with minor specific exceptions, the advertiser is not claiming an "adjunct sonic effect." The advertiser is not isolating the distinct features of its product as they pertain to its efficacy. Rather it is routing the mode of operation and performance of its product as a single unit, an entire activated toothbrush. It is, therefore, unwarranted to impose on the advertiser the duty to dissect the mode of operation of its device from its function.

The action of the vibration of the bristles of the Sonicare is an integral part of the plaque removal action of the brush, and dynamic fluid activity stems from that mechanical action. Optiva emphasized that it does not claim that the enhanced cleaning of the Sonicare is due only to sonically induced fluid dynamics effects.

One exception to this is the claim, “Sonicare surpasses direct brushing technology to *sonically clean teeth.*” Since this claim could be interpreted to imply a “sonic” effect on teeth that has not been established by the advertiser (at the exclusion of other mechanisms) the NAD recommended that the latter half of this claim be modified or discontinued.

IV. The issue of whether the Sonicare was inaccurately compared to professional cleaning devices or the process of flossing

NAD acknowledged that the statement “two minutes [with Sonicare] is equal to a consistent flossing and brushing program...” that was made in live radio advertising was an inadvertent statement reflecting the opinion of the speaker and was not endorsed by Optiva. Since this statement was made in connection with the promotion of the Sonicare, the advertiser appropriately took measures to discontinue the use of such unauthorized copy.

Based on information that it received from the advertiser, NAD concluded that Paul Harvey’s comments are no longer at issue for they have been formally discontinued.

V. The issues stemming from the advertiser’s reliance on its survey of dental professionals

The NAD disagreed with the challenger’s assertion that the survey of dental professionals upon which the advertiser relied was flawed. NAD accepted the method by which the survey was conducted as a valid means of obtaining product relevant information from an identified population. NAD also noted that the rare of response to this request for feedback was quite impressive. But NAD did have some concerns about the way these findings were communicated in the advertising.

Of the over 4,000 dental professionals who responded to this survey, 98% indicated that they would recommend the Sonicare to most or some of their patients. As the advertiser correctly pointed out, the universe to which these claims pertain is expressly identified by the claims themselves. In other words, the relevant universe is expressly limited by the claims at issue to “dental professionals who have tried the Sonicare.”

NAD’s concerns on this issue were not related to the extrapolation of the survey’s finding to the identified universe. Rather, the NAD was concerned with the literal meaning of the claim “98% of the dental professionals who have tried the Sonicare would recommend it.” It seemed to the NAD that the advertiser’s attempt to be exact and accurate failed in this instance. Through this claim, the advertiser explicitly quantified (98%) the number of “dental professionals” from the identified universe (those who have tried Sonicare) who would recommend it. All the dental professionals who tried the Sonicare were not part of the group from which the percentage was calculated. The 98% was derived from the group of dental professionals who responded to the survey. NAD realized that there was a significant response rate to this survey and that the results derived therefrom could be extrapolated, on a ratio basis to the identified universe. However, by assigning a specific numerical value, like 98%, to this finding, the advertiser did more than extrapolate the results, it redefined the universe on which its claim was based. Therefore, the NAD suggested that in the future this claim be modified to more accurately reflect that it refers to 98% of the respondents to the survey and not 98% of the dental professionals who have tried Sonicare.

VI. The issue of whether the advertising contained “unfounded superiority claims”:

The advertiser informed the NAD that many of the claims cited by the challenger as “unfounded superiority claims” have been permanently withdrawn. It assured the NAD that the only claims that are currently in use are those that have been accepted by the ADA. NAD also noted that the challenger did not present sufficient information to establish that those claims were comparative claims that rose to the level of superiority not that they were “unfounded.” NAD concluded that, within the context of the ads, certain of the claims listed by the challenger were at best “product descriptive” and any connotations of exclusivity that could have been inferred from them were based on the patented technology of the advertiser’s product.

THE BRAUN CHALLENGE

Braun Inc.'s Position: Braun categorized its challenge into four specific areas with regard to the claims made by Optiva. They have been designated as follows:

- 1) unique, "beyond the bristle" cleaning attributes based on sonic waves or "cavitation" action;
- 2) claims of product superiority compared to power plaque removers;
- 3) specific product performance attributes such as stain removal and "total cleaning"; and,
- 4) professional use and preference claims

Unique, "beyond the bristle" cleaning: According to the challenger, Optiva's advertisements state that its Sonicare toothbrush can clean areas of the teeth located beyond the bristle reach of manual toothbrushes and power plaque removers via a "unique" high frequency sonic wave technology that creates a "cavitation", more readily described by Braun as "a stream of highly pressurized, fast moving bubbles, capable of causing a cleaning effect without brush contact".

The challenger adamantly disputes the performance results claimed by the advertiser and submitted a clinical study to NAD (the "Grossman" study) to refute Optiva's assertions regarding the ability of its toothbrush to remove plaque and control gingivitis.

The Grossman study was conducted among 116 participants over a two month period and directly compared the ability of Sonicare to remove plaque and control gingivitis with that of an oscillating/rotating electric toothbrush (i.e., the Braun Oral-B Plaque Remover). The study was randomized and single-blinded with one examiner recording all plaque indices and a second examiner recording all gingival indices. At baseline each volunteer received a complete oral examination and supragingival plaque and gingival conditions were assessed. Data was also tabulated from the subjects after one and two months at 6 sites on each tooth in mouth. Plaque was measured using the Turesky scoring method and gingival condition was assessed according to the Loe and Silness Index.

The challenger's analysis of the results revealed that the Braun Oral-B Plaque Remover reduced plaque at all sites by 36% at one month and maintained the same reduction level after two months. Sonicare had a similar one month reduction score but its value fell to 30% at two months. Additionally, plaque removal at anterior lingual sites was reduced by 43% in the Braun electric toothbrush group as compared to 35% in the sonic toothbrush group. Plaque removal at interproximal sites was also found to be greater in the Braun electric toothbrush group and when all interproximal sites were analyzed there was found to be a 31% reduction in the Braun electric toothbrush group compared to 26% in the sonic toothbrush group. This difference did not achieve statistical significance.

After 8 weeks of use there was found to be no statistically significant difference in either plaque removal or gingival index between the two groups which suggested that the Sonicare toothbrush was no more effective at removing supragingival plaque than the Braun Oral B Plaque Remover "although previous studies have demonstrated that both devices are superior to manual brushing." Furthermore, the study concluded, that "the possibility that the Sonicare toothbrush is able to remove interproximal plaque by acoustic action beyond the bristles, as suggested by in vitro studies, does not appear to be supported by the data here."

The challenger maintained that the results proved that the Sonicare brush provided no advantage over Oral-B in removing plaque in the interproximal and lingual areas and provided no material improvement interproximally where Optiva claimed to remove plaque by fluid acoustics beyond the bristles.

In further support of its position, Braun submitted two stain removal studies. The first study (the "Schemehorn" study) compared Sonicare and the Oral-B Plaque Remover to measure the ability of each instrument to remove laboratory composed stain from 16 enamel specimens. The positive control consisted of an ADA reference abrasive and a manual toothbrush.

The 16 specimens were divided into groups of 8 with each group having the same baseline score. Four separate stain determinations were made on each specimen with the average used as the specimen score. After being placed on a V-8 mechanical cross-brushing machine, specimens were brushed for 4.5 minutes with 150 grams of force. Following the test brushing procedure, the specimens from all groups were rinsed, re-scored for stain and the study was repeated with a second set of 8 specimens in each group.

According to the challenger, the results illustrated that stain removal with the manual brush and with the Sonicare brush was statistically less effective than the ADA reference standard and the Braun Oral-B Plaque remover ($p < 0.01$). There was no statistical difference between stain removal with a manual brush and with the Sonicare.

A second study (the "Moran" study) also compared the stain removal efficacy of Sonicare and the Oral-B Plaque Remover as compared to a manual brush. The Moran study was a single blind, crossover design involving 24 subjects and measured removal of extrinsic stain, tongue stain, calculus formulation and pre and post brushing sensitivity. Stain was formulated over a 21 day period by twice daily rinses of chlorhexidine and frequent intakes of tea and coffee.

The study was divided into three 21 day periods, each of which was followed by a seven day washout period before subjects changed to a different toothbrush. During each brushing period, the testing participants were instructed in the use of each respective toothbrush and instructed to brush twice a day for two minutes. At the end of each brushing period the measurements were again tabulated.

Analysis of the results revealed no significant difference in tooth stain intensity following use of the three brushes. However a significant reduction in mean total stain area was noted following use of the electric brush (Oral-B) compared with the manual brush and Sonicare. There were no significant differences between the toothbrushes for interproxinal stain scores but the results showed significantly less tooth sensitivity following use of the oscillating/rotating brush, compared to both the manual and sonic brushes.

According to Braun, the tests show that extrinsic stain removal is not greater for Sonicare than that achieved with either the Oral-B Plaque Remover or a manual brush and no other studies could affirmatively identify the ability of Sonicare to clean areas beyond the bristles of the toothbrush.

The challenger also objected to Optiva's use of the term "cavitation" in the advertising and explained that cavitation bubbles are different from the bubbles or foam which is generated by toothbrushes in the presence of toothpaste. Braun submitted five sets of data (as well as one of Optiva's U.S. Patents) to refute the advertiser's assertion that the "fast moving bubbles" described in Sonicare's advertising are cavitation bubbles, but are instead "ordinary foam propelled by fluid streaming" which does not produce enough activity to clean debris from solid surfaces.

According to Dr. A.R. Williams' expert evaluation, it was indicated that the acoustic energy necessary to produce cavitation is approximately 0.5 atmospheres (RMS) and that "the small amount of acoustic energy generated by Sonicare (approximately 0.02 atmospheres (RMS)) 'is not enough to drive gas bubbles to the point where they can generate hydrodynamic forces which can assist the cleaning process.'"

In support of its argument that Sonicare does not produce a cavitation effect, Braun submitted a video and an accompanying study to illustrate that Sonicare and the Oral-B Plaque Remover produced comparable "beyond the bristle" fluid forces and foaming activity, which have nothing to do with sonic waves.

Similarly, the challenger argued that its data demonstrated that the sonic waves do not contribute in anyway to plaque or stain removal or foaming activity and that Sonicare removes plaque the same way as conventional brushes - by bristle contact. Braun noted that since Sonicare operates at the same frequency range (200-500 Hz) as "prior art power toothbrushes", that its beyond the bristle cleaning activity must be attributed to some other factor.

Superiority Claims: As illustrated by the Grossman, Schemehorn and Moran studies briefly described above, it is the position of Braun that Sonicare is unable to support the following claims of superiority:

- a) "sonicare surpasses direct brushing technology to sonically clean teeth",
- b) Direct comparisons to the "best manual and electric toothbrushes";
- c) "Sonicare- a clinically proven sonic innovation that takes oral care a step beyond", and;
- d) "... more complete cleaning in high risk areas"

More specifically, the challenger believed that the above claims are false and misleading in the context of the advertising, especially when used in unison with claims of uniqueness, professional preference and extraordinary performance.

Product Performance: It was Braun's position that the Schemehorn study also emphatically disproved Optiva's claim that the Sonicare toothbrush will remove 80% of stains resulting from coffee, tea and tobacco. While concluding that the stain removal properties of Sonicare were statistically equivalent to that of a manual toothbrush, Schemehorn also found that the shape of the Sonicare bristles, in combination with its high frequency and low amplitude motion, negatively impacted the stain removal propensities of the toothbrush. Braun also noted that the comparative data from the Moran study corroborated the conclusion of Schemehorn that Sonicare did not remove stains better than manual brushing and was not superior to other electric toothbrushes.

The challenger also alleged that Optiva's claim that Sonicare "reaches deep for total cleaning" was also misleading. A literal interpretation of the claim would mean that (as is the case in a dental prophylaxis cleaning) all plaque is removed and unless Optiva could provide evidence of 100% plaque removal, the claim must be unsubstantiated. Despite the advertiser's offer to remove the word "total" from the claim, Braun still believed the statement "would imply parity with dental tools, especially given the professional testimonial ("One Michigan Dentist writes, 'I have never used an instrument which so totally removes plaque.'") that follows the claim in the text of the advertisement.

The challenger cited the FTC Guidelines to support its assertion that it has been well established that a testimonial claim must be representative of typical results. According to Braun, the testimonial "claims that Sonicare removes 100% of plaque and does so in a manner which is actually better than standard dental instruments." As stated above, the challenger insisted that no such evidence exists and, accordingly, that the advertiser has no reasonable basis for the claim.

Professional Use and Preference Claims: Braun argued that the professional preference claims made by Optiva which stated that an overwhelming number of dental professionals who have used Sonicare prefer it for their own and/or their patients use, were intrinsically tainted because the survey methodology was shown to be inherently susceptible to predisposed results.

The challenger questioned the reliability of the data because it was directed "only at recent purchasers of the product" who would thus "be severely biased in favor of the purchased product by virtue of the recent acquisition." Braun noted that the advertiser's survey was not conducted on a blind basis and that its respondents at all times knew the sponsor of the survey.

The challenger submitted a copy of the Sonicare "trial card" which it believed demonstrated a purchaser bias that affected the survey. Optiva offered to sell dental professionals its toothbrush at a 75% savings and gave recipients the option of returning the product after a thirty day trial period. It was stressed by the challenger that "triers" and "purchasers" are not one and the same. It was Braun's position that a valid survey could not be premised on the responses of a portion of the population which was biased in favor of a particular viewpoint - a viewpoint obviously clouded by a discounted purchase.

The challenger pointed to the minuscule 2% of professionals that returned the product as evidence of a skewed testing sample, which essentially consisted of "[a group of select] professionals who were in the market for an electric toothbrush and obviously had no preferred toothbrush in their possession." This, in turn, led to the conclusion that such a sample group (i.e., 95% of whom have tried at least one other brand...) was inherently biased because it was clear that they were individuals who were not satisfied with their present electric brush and that those who were satisfied would be less inclined to try a new product. Accordingly, those who returned the questionnaire were primarily those who bought the product and the testing universe became not "dental professionals" but instead "discount purchasers of Sonicare who were dissatisfied with their current toothbrush".

Braun's criticism of testing data submitted by Optiva's support of its performance claims: In response to Optiva's description of the "cavitation and fluid streaming" effect of Sonicare, the challenger contended that the "fast moving bubble activity" (i.e., fluid streaming) is not cavitation but, in fact, foaming due to "the air into the fluid."

Braun disputed the control procedures employed in the in-vitro studies submitted by Optiva to substantiate its "beyond the bristles" claim, and maintained that there was no way to determine whether the results obtained in these studies were unique to Sonicare as compared to other power toothbrushes.

The challenger also raised the issue of whether the conclusions derived from Optiva's studies "are predictive of any in vivo 'beyond the bristles' effect." Braun alleged that there was no evidence submitted by the advertiser to demonstrate that the adherence properties of the bacteria strains to the disks used in the studies were comparable to the adherence of plaque to tooth enamel in-vivo. Accordingly, the adherence strength of the bacteria to the disks used in Optiva's studies were unknown and "as far as we know, the bacteria could easily have been removed by water.

Braun noted that neither of the in-vitro, "beyond the bristle" studies investigated the effect of toothpaste, which the challenger believed "would increase the viscosity of dental fluid" and, as proof, quoted one of the authors of the study who stated that "the dynamics of brushing in the oral cavity will be different than an in-vitro situation, i.e., saliva and toothpaste may alter the fluid dynamics, fluid quantities around the brush head may vary..."

The challenger also questioned the exposure time and fluid medium that were used in the in-vitro the studies. In one study the brushing time was 120 seconds and in a complete fluid medium, neither of which relate to normal brushing conditions. Because Optiva recommended a two-minute brushing period for the entire mouth, the challenger estimated that the exposure time used in this study was 60 times longer than ordinary brushing. The exposure time used in the second study was 15 seconds which, according to Braun, was 7 times the contact time of normal brushing.

The challenger objected to the statistical method that was used by the advertiser in analyzing the data. The conclusion that Sonicare reduced the bacteria beyond the bristles was based on a median count. Braun maintained that bacterial count data "are known to display considerable skewness (i.e., vary asymmetrically around the mean), and that proper analysis of the Optiva's data is dependent on the assumption that "distribution about the mean is symmetrical."

The challenger also criticized Optiva's second comparative study (McInnes II) for a number of reasons. First, Braun noted that the advertiser compared Sonicare with Interplak and the UltraSonex to bias the study results in favor of

its product. Braun argued that the two competitive brushes in the study produce very little fluid streaming or foaming activity.

The Melness study is further suspect because it only provides plaque removal data at 3mm as opposed to Optiva's first study which presented removal data at four different measurement points, including 4mm. Braun also raised the same exposure and fluid medium objections that were made in its observation of Optiva's in-vitro studies, and which were addressed more specifically in the proceeding paragraphs.

According to the challenger a third study ("Stanford") submitted by Optiva which compared Sonicare and Interplak was also flawed because of exposure time (15 seconds) and the absence of dentifrice, and, similarly, only measured plaque removal at 3mm. Additionally, Braun contended that the advertiser's test contained only six enamel sections (in different sections of the mouth) which meant only three of those sections were used as control -too small a sample size from which to draw definitive conclusions.

The challenger also maintained that Optiva's two studies on bacteria reduction in periodontal pockets lacked sufficient control and Braun's expert analyst noted that "the reduction in subgingival bacteria may be explained by the reduction in pocket depth and gingival inflammation and not necessarily on cleaning beyond the bristles into the pocket." Braun further disputed the data relied on by the advertiser to support its claim to reduce coffee, tea, tobacco and chlorhexidine stains and maintained that the very small sample sizes may have provided unreliable information. In Optiva's first ("Peridex") stain test, Sonicare's subjects had significantly higher baseline scores and Braun alleged that this resulted in Sonicare's greater stain reduction as compared to the median baseline measurement. According to the challenger, "no difference in stain removal between Sonicare and manual toothbrushes was apparent from the *mean* data reported." Braun also inquired about the increase in stain after two-weeks, which could have implied that factors other than toothbrush use were contributing.

The challenger argued that the statistical data was also incorrectly tabulated in Sonicare 's second stain study ("Johnson II"). Braun stated that the data was not analyzed for co-variance and that "the mean computer data would suggest that Sonicare was slightly less effective than a manual brush". It also contended that the study using electron microscopy ("Tufts") failed to adequately explain how Sonicare removed stains from cracks and fissures in enamel by "fluid dynamic action and mild cavitation", especially when the toothbrush was used in conjunction with an abrasive dentifrice. Lastly, this study used only three extracted teeth, which Braun believed to be too small a sample size from which to project significant statistical conclusions.

Braun disputed the advertiser's statement that its clinical plaque removal studies provided "a strong and compelling scientific basis" that Sonicare "offers unique benefits," "thereby surpassing their [Braun's] technology." The challenger asserted that the testing was inadequately controlled (only a manual brush was included), did not have a preferred group distribution (twice as many men as women) and failed to report any pre-brushing scores for comparative purposes. Furthermore the gingivitis scores (the only data reported in connection with home use) demonstrated that Sonicare "did not control plaque to sufficiently higher level than the manual brush to show a significant effect on overall hygiene or dental health."

The Optiva Corporation's Response to the Braun Challenge: According to Optiva, the Sonicare toothbrush utilizes an electro-magnetic driving system to produce high frequency, low amplitude bristle activity resulting in approximately 31,000 strokes per minute. The advertiser has claimed that its brush removes plaque and stain not only by mechanical action but also by acoustic fluid action that occurs up to 4mm beyond the bristle tips.

Beyond the Bristles Cleaning: The advertiser submitted a number of studies to illustrate the ability of Sonicare to clean oral surfaces beyond the reach of the toothbrush bristles. The first study ("Melness I") attempted to illustrate the effect of low acoustic energy on adherent bacteria (i.e., A. viscosus). After staining, a bacterial suspension was exposed to acoustic energy from both a laboratory generator (200Hz) and the Sonicare toothbrush (260Hz).

Examination with electron microscopy observed that the shear forces occurring in the exposed fluid due to bubble activity and fluid flow were likely to damage sensitive surface structures on the surfaces of the bacteria.

The second set of studies ("Wu-Yuan") were submitted to determine if fluid agitation alone could dislodge bacteria from oral surfaces. Titanium discs coated with oral bacterial plaque were used as a model dental surface and exposed to Sonicare-induced fluid forces. Electron microscopy quantified results at 0, 1, 2, 3, and 4mm distances. The data showed that after 15 seconds of direct bristle contact nearly 100% of bacteria was removed from the dental surfaces, with an average of 75% reduction at a distance of 2mm. Optiva stated that the tests further indicated that 61% and 24% of two different types of bacteria were removed at 4mm. The results were significantly different from the control at ($p < 0.05$).

The advertiser also conducted a confidential, in-vitro comparison of the beyond the bristle capabilities of Sonicare, Interplak and UltraSonex ("McInnes II"). Using exposures of 5 and 15 seconds at 3mm distances between bristle tip and disc surface, the results (which allowed for a 5% variability) showed that the competitive brushes removed less than 5% of the oral bacteria, while Sonicare removed 41% (at 5 seconds) and 69% (at 15 seconds) respectively.

Optiva submitted two confidential studies on the reduction of bacteria in periodontal pockets. In the first of these studies ("Johnson I") plaque samples were taken from two periodontal sites on 10 subjects. After two weeks, the statistically significant results showed that Sonicare demonstrated a significant ability to suppress the subgingival flora.

The second study ("Ortblad") investigated the repeatability of the first study to determine if the bacterial counts remained at lower levels over a longer brushing period. Using 10 subjects with pocket depths of 5 to 7mm, Sonicare was shown to reduce the numbers of bacteria significantly over an 8 week period.

The advertiser also submitted confidential in-vitro testing to study the fluid pressure near the Sonicare bristle tips in various geometric configurations (i.e., a test well and an oral cavity model). Records of the sonic fluid pressures in the test chamber and on a typodont tooth face and interproximal region demonstrated similar pressure and provided a conservative measure of fluid dynamics surrounding the Sonicare bristles.

A confidential videotape submitted by Optiva visually compared the fluid dynamics of Sonicare and other electrical toothbrushes to illustrate Sonicare's cavitation and fluid streaming effects. The advertiser maintained that the generation of these effects "provide the beyond the bristles cleaning that occurs with Sonicare."

Product superiority claims: It is the position of Optiva that because Sonicare cleans teeth differently and offers "unique benefits" that manual and electric toothbrush do not, that as a result, it "surpasses" conventional technology. According to the advertiser, conventional electric toothbrushes clean by the direct scrubbing of its bristles against the surface of the tooth. Sonicare also cleans by scrubbing (albeit with less force than competitive brushes) as well as by creating "fluid dynamic forces which flush and remove debris and plaque bacteria beyond the physical reach of the bristles."

Optiva submitted two in-vivo studies to demonstrate the ability of Sonicare to remove plaque in inter dental areas more effectively than a manual toothbrush. The first study ("Johnson II") consisted of 51 subjects randomly assigned to one of two groups. Plaque scores were assessed at baseline, 1, 2, and 4 weeks. Gingivitis and sulcular bleeding scores were also taken at each evaluation. The analysis of plaque indices revealed a significant difference between the two devices over time ($p < 0.01$) with the sonic toothbrush indicating a greater level of plaque removal on all surfaces, with the most noticeable improvements in the interproximal and lingual regions. Sonicare also attained reductions in gingival inflammation similar to that of a manual brush.

Sixty subjects participated in the second comparative study ("Tritten") of Sonicare and a manual brush. Using the Turesky's modified Quigley-Hein index, plaque scores were measured at baseline, 1, 2, 4 and 12 weeks. Gingival

inflammation was also assessed using the Loe and Silness Index and Bleeding Tendency Score. The results showed Sonicare to be statistically superior in removing supragingival plaque ($p=0.012$), particularly on posterior teeth ($p=0.003$) and in interproximal regions ($p=0.004$).

The advertiser also maintained that the claim “[Sonicare is] a clinically proven sonic innovation that takes oral care a step beyond” was not intended as a quantifiable performance claim and should be accordingly treated as advertising puffery.

Stain Removal and Cleaning claims: Optiva advised NAD that the claim “...reaches deep for total cleaning and brightening...” had been modified by dropping the word “total” and removing the phrase “...but without the unpleasant scrape of a dental tool.” Thus, it is the advertiser’s position that the challenger’s objections to this claim are moot. Optiva relied on the studies that it submitted to support its “beyond the bristles” claim (which were more specifically detailed above) to also prove its claim that “Sonicare foam reaches deep”. The claim stating that Sonicare “removes over 80% of coffee, tea and tobacco stains for naturally whiter teeth” was based on a University of Washington study using 19 subjects with intrinsic stain due to coffee, tea or tobacco. The subjects were randomly assigned into a Sonicare group or a manual brush group, and evaluated using the Lobene index (which quantifies stain using a criteria of intensity and area) at pretrial, 2-week and 4-week periods. Both devices showed comparable reduction after the 2 week evaluation, but after 4 weeks the reduction in stain was 82% for Sonicare versus 39% for the manual brush. Both groups were significantly different from baseline ($p<0.05$). The advertiser noted that stain removal was also evaluated using computer image analysis, which provided a highly quantitative measure of stain area. Optiva’s claim that “Sonicare achieved more than a 50% reduction in stain caused by a common oral prescription (chlorhexidine)” was supported by a University of Pennsylvania test of 30 subjects over a 4 week period. After initially using a 0.12% Peridex mouth wash to accumulate stain, it was determined (using the same Lobene index) that use of Sonicare resulted in a 54% reduction after two weeks and 50% reduction after 4 weeks as compared to the manual brush which resulted in no removal after 2 weeks and a 24% increase of stain by 4 weeks. The advertiser also submitted the report of a confidential in-vitro study that assessed the stain removal capacity of Sonicare and the fluid activity around the bristle tips by employing an environmental scanning electron microscope and using 12 extracted molar teeth. The teeth were stained both extrinsically and with Peridex. Optiva asserted that the results of this test illustrated that after a 60-80 second exposure to Sonicare all visible stain was removed from the teeth.

Professional use and preference claims: Optiva maintained that the testimonial statement from the Michigan dentist (“I have never used an instrument which so totally removes plaque”) had been approved by the American Dental Association (ADA) and was supported by the clinical and laboratory studies that were submitted in substantiation of its other claims. Furthermore, the advertiser contended that the testimonial “fairly reflects not only the personal experience of the source dentist, but also the typical experience of dentists who have tried Sonicare. The advertiser submitted a copy of the dentist’s letter (containing the claim in question) which it believed made clear that the dentist was referring to Sonicare as an instrument used personally at home without comparison to in-office dental instruments and that the consumer-directed context of the advertisement reinforced this position. The advertiser also noted that Bausch & Lomb refers to its product as the Interplak Home Plaque Removal Instrument and that even Braun referred to its own product as an “instrument” in its product labeling which states that the Oral-B Plaque Remover is “Shaped like a dentist’s cleaning instrument.” The advertiser maintained that the survey upon which the preference claims were based is the same one currently used by the challenger and was reviewed in prior NAD challenges (the claims were substantiated). The 98% recommendation and 92% preference results were all fairly and accurately represented in the advertised claims and “are consistent over time and across all sub-segments of the professional trier audience.” Optiva stated that its survey is routinely mailed to all dental professionals who purchase a trial Sonicare toothbrush and informed NAD that only 2% of purchasers return their sample units. The advertiser additionally noted that 95% of the dentists surveyed had tried at least one other brand of power assisted plaque remover. The testing universe was described in the advertisement as “dental professionals who have tried Sonicare” and Optiva stressed that this fact was properly identified in the ad. Moreover, the advertiser stated that a representative sample size was taken (i.e., all dental professionals who tried the Sonicare product). Thus, according

to the advertiser, all members of the universe were contacted. Over 4,000 dental professionals (consisting primarily of dentists and hygienists) responded to the survey, a rate that the advertiser's expert said was "well within the range of industry norms for mail surveys in general and especially good for surveys of dental professionals."

Optiva's Criticism to Braun's Testing Data: Beyond the Bristles Cleaning: According to the advertiser, the Grossman study submitted by the challenger did not disprove Sonicare's "beyond the bristles" claim of removing plaque bacteria and was fatally flawed for a number of reasons. First, Optiva objected to the scoring methodology used by the Braun test, stating that it would have been impossible to reach a conclusion regarding the ability of Sonicare to remove plaque by acoustic, fluid dynamic action. The plaque scores were collected 24 hours after accumulation and no post brushing scores were tabulated rendering it impossible to accurately discern any difference between the two products. Additionally, the modified Turesky method of calculating plaque build up is a measurement of area and not a "plaque volume" measurement. The advertiser reasoned that it was possible that Sonicare's beyond the bristles cleaning effect reduced plaque volume, while plaque area was less effected. Optiva also questioned Dr. Grossman's statement that the testing subjects did not have any testing experience, especially if Dr. Grossman has conducted "over one hundred studies". According to the advertiser, it would seem likely that the subjects had participated in previous Oral-B studies. Optiva responded to the challenger's assertion that gingival scores would have improved if a reduction in bacterial counts "beyond the bristles" actually occurred, by quoting from one of Oral-B's reports which stated that plaque and gingivitis scores are not necessarily linearly related, and that "...gingivitis itself does not progress in a linear fashion and indeed may go through peaks and valleys of severity during any period of time."

Stain Removal: The challenger relied on the Schemehorn study to disprove the efficacy of Sonicare with respect stain removal. However, the advertiser responded that the 150 grams of force applied during the test is known to stall the bristle movement in its product and, consequently, decrease its overall effectiveness. Although Braun stated that a mean brushing force of 50 grams is "impossible", Optiva asserted that this contention is not supported by scientific evidence. The advertiser further noted that it had tested Sonicare users and that the average brushing force applied was 67 grams.

Optiva also added that the artificially stained sections of cows teeth that were used in the Schemehorn study, was of questionable relevance to real stain on human teeth and that its own testing had been conducted on actual stain formed in-vivo on human teeth.

The advertiser believed that Braun's reliance on the Moran study was similarly displaced. Optiva questioned the relevance of only six instances of statistical significance - when a total of 48 significance tests were done - and maintained that "It is customary to require a more stringent alpha level or to use a multiple comparisons adjustment procedure to guard against erroneous conclusions of 'significance' in situations where large numbers of comparisons are done on subjects of the same overall data set."

Optiva maintained that irrespective of the results of the Moran study, that it had not made stain removal superiority claims as against Braun. Conversely, it had only claimed that Sonicare removed 80% of coffee, tea and tobacco stain and 50% of Peridex (chlorhexidine) stain pursuant to its published clinical studies.

Cavitation: The advertiser, first and foremost objected to the challenger's data regarding cavitation because it was not part of Braun's original submission and was not responsive to any of the issues initially raised at the outset of the challenge.

The advertiser defended its use of the term, nevertheless, and maintained that the challenger's definition of cavitation was being narrowly applied. It was the position of Optiva that there are several types of cavitation and the effect created by Sonicare under low pressure must be distinguished from the "vaporous cavitation" that occurs at high pressure.

In its advertising copy, Optiva qualified Sonicare's cavitation effect as being "mild cavitation" and also maintained that it has responsibly communicated that its product produces low pressure, gaseous cavitation rather than high pressure "vaporous cavitation". The advertiser added that its product's effect (i.e., mild cavitation) had been admitted in Braun's own expert analysis.

The advertiser also rebutted Braun's statement that its product has "substantially identical sonic waves" to Sonicare. Besides the frequency difference (261 Hz for Sonicare vs. 48Hz for Oral-B), Optiva's product has more than 5 times the average rip velocity, substantially more fluid sonic pressure and requires less force to be used during the average brushing. The advertiser also believed that Braun failed to demonstrate that the Oral-B electric brush produced abundant fluid cavitation as compared to Sonicare. The challenger's criticism that Sonicare's effectiveness ceases when the toothbrush is fully immersed in the water, is of no credence because it was atypical of the in-vivo situation and attempted to replicate a completely unrealistic environmental condition.

Optiva asserted that its own clinical and laboratory studies have all been peer reviewed and published in respected scientific journals. In response to the challenger's criticism regarding the plaque models used in Optiva's in-vitro studies (McInnes and Wu-Yuan), the advertiser stated that its studies included testing of the effects on natural human plaque as well as three strains of oral bacteria and that the adherence characteristics of the sample bacteria is well established in scientific literature.

- The challenger's comments concerning the brushing time (two minutes) employed in this study were also addressed by Optiva. The advertiser pointed out that the challenger mistakenly assumed that Sonicare only brushes one surface (of 64 "oral" surfaces) at a time. However, Optiva estimated that there are in fact only 25.6 brushing surfaces because Sonicare brushes at least 2.5 surfaces at a time (due to a longer brush-head and a scalloped bristle design) and thus each surface receives, instead, about 5 seconds of brushing.

Braun also questioned why the Oral-B Plaque Remover was not included in the comparative bristle study (McInnes II) conducted between Sonicare, Interplak and Ultrasonex. Optiva stated that it chose the Interplak because it produced-more fluid dynamic activity than the challenger's product and submitted a report to verify that a minimum of twelve replications were performed for each condition.

With respect to the Peridex test, the advertiser addressed the challenger's concern about greater chlorhexidine stain at baseline in one group as compared to the other. It stated that the buildup of chlorhexidine varies depending on the individual. Still, if a subject has more stain it does not mean that the stain will be easier to remove (as contended by Braun) but instead a darker stained area will "demonstrate greater stain accumulation which has likely been on the tooth longer, and are generally more difficult to remove."

The advertiser also maintained that post-brush evaluation was the appropriate method to meet the goals of its testing. This method of plaque scoring allows for:

- a) a better indication of the amount of plaque removed both on a daily basis as well as over a substantial period of time, and;
- b) accounts for variations of plaque build-up by different individuals and since the time of last brushing.

Preference claims: The advertiser contended that the fact that the survey was not blinded is irrelevant because the testing universe (dental professionals) was highly knowledgeable about the product and had a high level of interest in the product category. According to Optiva, "Blinding has relevance for broad consumer surveys in which participants are asked to give evaluations for products which they have no expertise...and could be susceptible to the knowledge of the study's sponsor."

It is the position of Optiva that its discounted trial offer to dental professionals would be unlikely to have any bearing on the beliefs of highly compensated professionals and that it is standard practice for dental professionals to receive discounts on "power toothbrush products".

In response to concerns that dentists who bought the Sonicare were atypical because they represented dentists "who were unhappy with their current product", the advertiser submitted an article from Dental Products Report, which included a survey that indicated that personal trial was the most important factor when choosing to recommend a power assisted toothbrush. As an indication of competitor satisfaction, Optiva made reference to dentists surveyed who were currently selling the Oral-B Plaque Remover to their patients. Among that subgroup, 98% reported that they would recommend Sonicare and 86% reported that they personally prefer Sonicare.

The advertiser also submitted a non-respondent survey of 200 randomly selected "triers" who received a Sonicare toothbrush but did not return the survey. The results showed a 94% recommendation rare, 82% who would personally select Sonicare.

NAD's Decision as to the Braun Challenge:

Beyond the Bristles: Evidence of this unique cleaning attribute of the Sonicare toothbrush was satisfactorily demonstrated to NAD by virtue of several in-vitro studies which, together, presented a reasonable basis to support the advertiser's "beyond the bristles" performance claims.

It was the conclusion of NAD that the advertiser's laboratory studies had one specific element that clearly distinguished it from the testing submitted by the challenger, that is, Optiva's tests focused directly on the beyond the bristles characteristics of the toothbrushes it examined. More specifically, the advertiser submitted reliable, statistically significant, in-vitro testing of its product to show:

- a) that fluid agitation alone could dislodge bacteria from oral surfaces;
- b) that acoustic energy generated from the Sonicare could remove bacteria both adherent to each other, as well as to saliva treated hydroxyapatite disks;
- c) comparative, beyond the bristle effects of three electric toothbrushes at 3mm and the laboratory removal of in vivo derived dental plaque from tooth enamel beyond the bristles as compared to Interplak;
- d) reduction of bacteria in periodontal pockets; and
- e) through the use of an environmental scanning electron microscopy, the removal of extrinsic stain within the narrow cracks and fissures of extracted teeth.

NAD also agreed with the advertiser that the comparative clinical tests submitted by the challenger were not purposely designed to assess cleaning capacity beyond the bristles. It appeared that the underlying objective of the Grossman study was to evaluate the overall ability of Sonicare to control plaque and gingivitis in a clinical situation. Thus, any incidental conclusions reached as to the "beyond the bristle" action of the toothbrushes with respect to plaque removal must be viewed entirely as such. Similarly, both the Schemehorn and Moran tests submitted by Braun were specifically designed to comparatively measure the stain removal efficacy of Sonicare and the Oral-B plaque Remover and not to detect beyond the bristle activity.

NAD does not dispute the legitimacy of the modified Turesky method used in Grossman to evaluate plaque removal in terms of "area" (by using a color-coded graph technique), however, it does believe that Optiva has raised a valid point in arguing that the challenger's test did not allow for the possibility that Sonicare's beyond the bristles effect reduced plaque volume, while plaque area was less effected.

NAD was also concerned about the pre-brushing analysis used in Grossman. Although test subjects were asked to brush for two minutes twice daily, they were also instructed not to brush for 24 hours prior to being examined for plaque accumulation. In the absence of a post-brushing examination for purposes of corroboration, it would seem a very real possibility that the accumulation of plaque during this non-brushing period could, even minimally, effect the test scores.

Optiva also satisfactorily addressed many of the challenger's criticisms concerning its beyond the bristle testing, more specifically those regarding the exposure time and the statistical methodology used in the study. While it was argued by Braun that the exposure time (120 seconds) used in the McInnes study (McInnes I) was not relevant to normal brushing conditions, Optiva explained that, because the Sonicare brushed 2.5 tooth surface at a time, the time exposure did approximate normal brushing time. Furthermore, the advertiser used a median bacterial measurement precisely to inhibit the tendency (i.e. skewness of -the bacteria count) suggested by the challenger.

Despite Braun's contention that Sonicare does not produce cavitation and that the "bubbles" generated by the toothbrush are simply "ordinary foam propelled by fluid streaming", it was apparent to NAD that the Sonicare toothbrush in its normal fluid environment did create some degree of cavitation, as it has been traditionally defined. According to Webster's Dictionary cavitation is defined as:

"the formation of partial vacuums in a liquid by a swiftly moving sound body or by high-frequency sound waves"

Optiva submitted an article to NAD that distinguished various types of cavitation and asserted that Sonicare produces an effect that is best described as "gaseous cavitation" which occurs in a low pressure environment. The advertiser produced competent scientific evidence to illustrate that the whipping action of the Sonicare bristles (which generate 31,000 bristle sweeps per minute) along with the mixture of saliva, water and an abrasive dentifrice create a buildup of sonic pressures between the teeth which also leads to "high velocity" fluid streaming that assists in the cleaning. As further proof of its cavitational effect, Optiva referred to presence of subharmonic signals in Sonicare (125Hz) that was illustrated in a report submitted by the challenger.

Although Braun submitted numerous tests to rebut this cavitational attribute of Sonicare. NAD did not believe any of these tests fully replicated normal brushing conditions. In two of Braun tests, the compared toothbrushes were completely immersed in water. Another test was conducted in a surfactant assisted environment and another evaluation of the toothbrushes was conducted without using dentifrice.

Most important to NAD is the context in which this "cavitations" claim appears in the advertisement. In each of the advertisements reviewed by NAD, it is clear that Optiva has described effect produced by Sonicare as "mild cavitation" and within the parameters of the evidence presented, this is a reasonable and accurate description. Moreover, there was no perception data submitted to show that either consumers or professionals were being misled by the claim.

NAD does agree with the challenger that Optiva has not submitted data to prove that the results of its in vitro, beyond the bristle tests could be replicated in vivo. Although some of the advertiser's beyond the bristle claims have been qualified by language indicating that this performance attribute has been observed in laboratory studies, alternatively, in other advertisements, this information has been omitted.

Accordingly, NAD recommends that although the advertiser's beyond the bristle claims, as they appear in the new advertisements, have been substantiated as a mode of action, all future advertisements should clearly disclose that this product characteristic has only been demonstrated in an in-vitro laboratory environment.

Product superiority claims: Although the advertiser made various performance claims regarding the technological and cleaning attributes of Sonicare in the "Sharper Image" and professional advertisements, NAD found that the

only direct or implied comparative claims that existed (besides the professional preference claims which are more specifically addressed in a later section) were comparisons to manual toothbrushes and that these claims were supported by Optiva with the appropriate clinical evidence. Additionally, without appropriate consumer communication data (which neither party submitted) to indicate otherwise, NAD would hard pressed to determine that the performance claims challenged in these advertisements reached a level of direct superiority.

The claim that Sonicare "surpasses direct brushing technology", has been satisfactorily qualified by the following sentence in the advertisement which describes the combination bristle contact/sonic vibration method that is used to clean teeth in different manner and in different areas (i.e., "beyond the bristles") than "traditional" toothbrushes. Despite Braun's contention that because the advertiser directly compares Sonicare to "the best" "electric toothbrushes", a false superiority claim exists, NAD disagrees. Optiva's claim simply describes the cleaning methodology employed by manual and electric toothbrushes to clean teeth (i.e., actual bristle contact) and then states that "...untouched plaque may remain where bristles don't reach."

However, NAD does agree with the challenger that in the "30 day free trial offer" advertisement, the claim "Achieve a more complete cleaning in high risk areas" may reasonably be interpreted by consumers to be a comparison inclusive of electric toothbrushes and based on the testing submitted by the advertiser, this has not be proven.

In its response to NAD, the advertiser defined this "high risk area" as the areas between the teeth (interdental sites). Although the advertiser did submit statistically significant clinical data indicating that Sonicare was superior at removing interdental plaque versus a manual toothbrush, no such evidence was presented that would indicate a similar conclusion as against an electric toothbrush. Accordingly, NAD believes that the claim "Achieve a more complete cleaning in high risk areas" may be interpreted by consumers as a cleaning superiority claim against all types of toothbrushes (i.e., electric toothbrushes) and that the advertiser should disclose the precise basis of the comparison to qualify the claim exclusively as against manual toothbrushes.

NAD does concur with the advertiser that its claim in the same advertisement which stated that Sonicare "takes oral care a step beyond" is one of puffery and not intended as an objective claim that would necessitate substantiation.

On the whole, NAD concluded that besides the one comparative claim in the "30 day free trial offer" advertisement (which should be modified as earlier described), that the remaining claims are no more than product descriptions which do not make direct or implied performance comparisons against other electric toothbrushes.

Product Performance Attributes: Although Optiva noted that the ADA had approved its claim that "The Sonicare foam reaches deep for total cleaning and brightening - but without the unpleasant scrape of a dental tool", it nevertheless agreed to modify the claim to read: "The Sonicare foam reaches deep for cleaning and brightening." Despite Braun's objections, NAD determined that the modification was entirely consistent with the evidence presented by the advertiser.

Having already concluded that the plaque and stain removal claims ("[Sonicare] removed 80% of stains due to coffee, tea and tobacco") of the advertiser were non-comparative in nature, NAD was left to determine if the results of the plaque and stain removal tests submitted by the challenger satisfactorily disproved the clinical and laboratory data submitted by Optiva in support of its claims.

The advertiser relied on the University of Washington in vivo test to substantiate its claim of 80% stain removal. The test was tightly controlled, conducted over a 4 week period and used a well accepted (Lobene) scoring index. Additional assessment of stain was provided by a computer image analysis.

The challenger submitted an in-vitro (Schemehorn) and in-vivo test (Moran) to rebut Optiva's specific stain removal claims. However, the advertiser detected a critical flaw in the Schemehorn test that caused NAD to seriously question the reliability of its results. The testing protocol stated that 150 grams of pressure were applied on the

toothbrushes during the examination, an amount which Optiva demonstrated would stall the bristle movement of its brush. The Sonicare's owner manual instructs the use of "light pressure" and Optiva recommends a pressure of about 75 grams.

Most importantly, it must be remembered that the advertiser is making a stain specific claim (i.e., coffee, tea and tobacco). Accordingly, the parties must produce evidence that it tested its products specifically against those stains individually named in the claim. The advertiser's test was distinctively a coffee, tea and tobacco stain study. Conversely, Schemehorn used a laboratory stain solution and in Moran, stain was enhanced by "twice daily rinses of chlorhexidine and frequent intakes of tea and/or coffee". While NAD is in no way proposing that the combined stain formulation used in the challenger's tests minimizes the results as to stain removal, in general, we do recognize that such studies do not provide an accurate gauge for the specific removal of those exact stains named in the claim. For instance, a twice daily rinse of chlorhexidine (traditionally a very difficult stain to remove) will inevitably affect the given scores in a stain accumulation test and any conclusion regarding the capacity of a toothbrush to remove another separate type of stain will be subsequently obscured.

A similar premise can be used in evaluating the applicability of Optiva's peridex study. The removal efficacy of both the Sonicare and a manual toothbrush were carefully evaluated in a well controlled clinical test using peridex stain. The results of this study were properly qualified in the advertised claim. It would be difficult for the challenger to rebut Optiva's claim of 50% reduction in peridex stain by submitting a test that used only a partial peridex stain.

In sum, as a result of the University of Washington tests, and because the specific type of stains were identified in the advertisement, NAD determined that the advertiser has provided a reasonable basis for its claims that Sonicare removed 80% of stains.

Professional Preference Claims: NAD has concluded that the testimonial claim of the Michigan dentist which stated that: "I have never used an instrument which so totally removed plaque" is in all respects consistent with the provisions listed in Section 15 of the BBB Code of Advertising, as well as those relevant sections in the FTC Guides Concerning Use of Endorsements and Testimonials Advertising.

The claim in context of the consumer advertisement does not appear to be deceptive or misleading. It is plainly obvious that the endorser is rendering an opinion based on his actual expertise as a dental professional and that his conclusion is based upon an expert evaluation of the product.

Notwithstanding Braun's objection that the endorser is comparing Sonicare to "professional dental tools," NAD found that the term "instrument," as it's used in the context of the advertisement, can be most reasonably construed as being inclusive of all consumer toothbrushes. In fact, the advertiser called NAD's attention to the fact that Bausch and Lomb refers to its product as "Interplak Home Plaque Removal Instrument". Thus, unless the challenger submitted evidence indicating that consumers were somehow being misled by the dentist's statement (which it did not), NAD would be remiss in not determining that testimonial from the Michigan dentist is a fair and genuine endorsement for the Sonicare toothbrush.

In evaluating Optiva's claims based upon its survey of dental professionals, NAD looked at two aspects in particular:

- a) the structure and methodology of the survey, and;
- b) representations made by the advertiser based upon the survey response.

Based upon the evidence in the case record it was clear that the universe that the advertiser's survey intended to represent ("dental professionals who have tried Sonicare") was appropriate in relation to the claim and that a representative sample (4,030 dental professionals) was chosen on which to base the results.

Although Braun objected to both the level of non-response (25% response rate) and the distinct possibility of gratitude/purchaser bias, NAD concluded that the type of survey conducted (mail) and the universe sampled (dental professionals) were two critical factors that had to be carefully considered in assessing the overall credibility of the survey.

The response rate of a survey is directly relative to the kind of survey that is conducted. That is, while a 65% response rate may be average in telephone or shopping mall survey, it would be unreasonable to determine that an identical response rate must be met in order to acknowledge the results of a different method of survey (i.e., mail). Additionally, NAD confirmed that a 25% response rate is average for the type of survey employed by the advertiser and the fact that Braun advertising, reviewed by NAD in 1994, used a survey which had only a slightly higher response rate (35%) cannot be ignored.

NAD agreed with the advertiser that dental professionals are not especially suspect to the ordinary purchaser bias that may exist in other surveyed groups primarily because it is customary in the industry to receive professional discounts of this type. NAD noted that 76% of the respondents did not take advantage of the opportunity to order a free Sonicare with the purchase of an additional unit which would also suggest that the discount offer did not bias the survey results.

Furthermore, NAD saw no reason to believe that knowledge of the survey's sponsor effected the responses of dentist professionals. Because of the high level of interest and expertise in the product category, a blind survey was not absolutely essential in garnering unsolicited comments from participants who are traditionally familiar with such methodology. The challenger's argument that Optiva's survey selected a subgroup of dentists who were unhappy with their current brand of electric toothbrush and were atypical of dental population is also suspect because (as stated in a relevant article submitted by the advertiser) the sampling of different products is a popular method used by dentists in keeping abreast of new technology in the industry.

NAD also verified that the questions used in Optiva's survey were clear and unambiguous and directly relative to the claims made in the advertising. Using a mix of both open and closed ended questions, the survey provided well-identified options for the respondents and allowed for the elaboration of personal opinion regarding product attributes and performance.

While NAD determined that the conclusions reached by the advertiser were a fair representation of the survey data, it also believed for purposes of accurate communication to consumers, that claims based on surveys of this type (i.e., those with low response rates) should be appropriately qualified by disclosing that is based on respondents to the survey. A literal interpretation of the advertiser's claim would be that "98% of all dental professionals that have ever tried Sonicare, recommend it to patients". Based upon the reported data, such an inference is not entirely accurate. In actuality, of the overall representative sample universe that was surveyed (i.e., approximately 16,000 dental professional that have tried Sonicare), 98% of the 25% that returned the survey (4,030) affirmatively indicated that they would recommend Sonicare. Based on these numbers, NAD determined that without further qualification (i.e., 98% of survey respondents), Optiva's claim was an overbroad projection of the data. The same premise holds true for the claim that "92% of dental professionals who have tried Sonicare prefer it for their own use." While NAD is not trying to minimize the 25% response rate of the survey (which is appropriate for this type of survey), it is asking the advertiser to convey a more accurate depiction of the survey.

As such, NAD finds that although the advertiser has met all the appropriate and objective standards necessary for a representative survey, that future claims should clearly disclose that its data is based on *respondents* to the survey.

Advertiser's Statement: "Optiva Corporation, makers of the ADA-accepted Sonicare toothbrush, is pleased that the NAD found its advertising claims to be principally substantiated. Optiva has invested considerable time, effort and expense in creating and evaluating the Sonicare®. Optiva's advertising claims are solidly based on laboratory and clinical scientific studies which demonstrate the capability of Sonicare

to remove dental plaque and tooth stains, and to reverse gingivitis. It is gratifying that the NAD has recognized the underlying validity of Optiva's scientific studies during its careful review of these challenges.

"Optiva will take into consideration, the minor clarifications suggested by the NAD in future copy. Optiva is pleased to have participated in the NAD self-regulatory procedures." (Sonex: #3229CS, closed 8/10/95; Braun: #3230PCM, closed 8/10/95)